DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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March 9, 2000

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 25

John W. Cain
President
Celletech, Ltd.
518 Tasman Street, Suite C
Madison, Wisconsin 53714

Dear Mr. Cain:

This letter is in reference to your firm's marketing and distribution of the products Tetanus/LM1, Nux Vomica, and Udder Symptom. Labeling for these products makes therapeutic claims that cause the products to be drugs under Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

Labeling for Tetanus/LM1 includes the disease name Tetanus and the statement, "This micro-dilution is intended for the treatment of illness." Nux Vomica is labeled for nausea and vomiting.

In addition, Nux Vomica is labeled as a "Homeopathic Medicine." Homeopathic drugs must be manufactured in accordance with the principles of homeopathy. Products manufactured through the use of your firm's "magneto-geometric process" or the [redacted] are not manufactured according to homeopathic principles and, therefore, are not homeopathic.

Tetanus/LM1 and Nux Vomica are "new drugs" [Section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications (NDAs) [Section 505(a) of the Act].

Udder Symptom, as formulated and labeled, is not generally recognized among experts as safe and effective for its stated uses and requires an approved New Animal Drug Application in order to be legally marketed in the United States. No such application has been filed and approved in accordance with Section 512 of

the Act. Therefore, the product is an unapproved new animal drug that is adulterated under Section 501(a)(5) of the Act.

Tetanus/LM1 and Nux Vomica are also misbranded because their labeling fails to bear adequate directions for the conditions for which they are offered [Section 502(f)(1) of the Act] and their labeling is false and misleading because it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established [Section 502(a) of the Act].

Further, Nux Vomica is misbranded because its labeling is false and misleading because it states that product is homeopathic when, in fact, it is not [Section 502(a) of the Act].

Udder Symptom is also misbranded under Section 502(e)(1)(A)(ii) and 502(a) in that the product fails to declare the established name of the active ingredients and it bears directions for use in children and adults. Directions for use in children and adults are misleading on a product labeled for mastitis.

In addition, your firm has indicated that it intends to continue to manufacture a large number of products using your "magneto-geometric process" and the [redacted] and to label and market these products as homeopathic. Such products will also be unapproved new drugs.

Further, homeopathic products may not contain non-homeopathic ingredients. Therefore, any products combining homeopathically prepared ingredients with ingredients generated by your [redacted] will not be homeopathic [FDA Compliance Policy guide (CPG) 7132.15].

Also, homeopathic drugs are not exempt from the requirements concerning the sale and labeling of prescription drugs. The price list for National Homeopathic Products offers a number of over-the-counter products with therapeutic claims that represent prescription drug indications. These include: shingles, Measles, Chicken Pox, thyroid, Candida yeast, and pink eye. Sale of such homeopathic drugs requires a valid prescription and a prescription drug legend on the product label.

This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated

by the Food and Drug Administration (FDA) without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

In addition, concerning the following products: Uterine Dysfunction, Inflammation S.S.C., Intestinal Illness, etc., Respiratory Illness in Cattle, Maintain Udder Health, Udder Symptom Relief, Fever I, Clean System of Antibiotics, First Symptoms, Reduce Cell Count II, and Uterus Toner, all the above products are intended for use in the treatment/mitigation/prevention of animal diseases and therefore meet the definition of "drug" under Section 201(g)(1)(B) of the Act. Promotional materials falsely imply FDA approval by referring to the NDC number as the "FDA Products #." All the above products appear to be in violation of the Act in that they do not bear adequate directions for their intended uses and they are not drug-listed with the Center for Veterinary Medicine.

Please notify this office in writing within 15 working days after the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to ensure that similar violations do not occur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented. Your reply should be directed to Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

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